PATENT COOPERATION TREATY 0 1 SEP 2004

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 0.5 MAR 2004

			WIPO PCT		
Applicant's or agent's file reference BW266R/RVP  See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)					
International application	No. International filing date 03.03.2003	• • •	Priority date (day/month/year) 01.03.2002		
PCT/IT 03/00120					
A01H5/00	ssification (IPC) or both national classification a	and IPC			
Applicant PLANTECHNO S.	R.L. et al.		·		
This international preliminary examination report has been prepared by this International Preliminary Examining     Authority and is transmitted to the applicant according to Article 36.					
2. This REPORT	consists of a total of 4 sheets, including to	nis cover sheet.			
This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).					
These annexe	s consist of a total of sheets.				
	<del></del>				
3. This report cor	ntains indications relating to the following i	tems:	and the second s		
I ⊠ Bas	sis of the opinion				
1	ority				
	n-establishment of opinion with regard to i	novelty, inventive step an	d industrial applicability		
}	ck of unity of invention				
V ⊠ Re	asoned statement under Rule 66.2(a)(ii) wations and explanations supporting such s	rith regard to novelty, inve atement	entive step or industrial applicability;		
	rtain documents cited				
VII □ Ce	rtain defects in the international applicatio	n			
VIII 🗆 Ce	rtain observations on the international app	lication			
Date of submission of	the demand	Date of completion of this	s report		
23.09.2003		26.02.2004			
preliminary examining		Authorized Officer	SECTION STORMS		
European Patent Office D-80298 Munich		Bilang, J			
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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IT 03/00120

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J.	Das	13	u.	III IC	100	VI L

1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

	Des	cription, Pages	
	1-29	•	as originally filed
	Clai	ms, Numbers	
	1-22	2	as originally filed
	Dra	wings, Sheets	
	1/8-	8/8	as originally filed
Se	que	nce listing part of the	e description, pages:
1-9	9, as	originally filed	
2.	With	n regard to the <b>langu</b> a juage in which the inte	age, all the elements marked above were available or furnished to this Authority in the ernational application was filed, unless otherwise indicated under this item.
	The	se elements were ava	ailable or furnished to this Authority in the following language: , which is:
		the language of a tra	nslation furnished for the purposes of the international search (under Rule 23.1(b)).
	. П.	the language of publi	ication of the international application (under Rule 48.3(b)) : :: :::::::::::::::::::::
		the language of a tra Rule 55.2 and/or 55.3	nslation furnished for the purposes of international preliminary examination (under 3).
3.	With inte	n regard to any <b>nucle</b> rnational preliminary e	otide and/or amino acid sequence disclosed in the international application, the examination was carried out on the basis of the sequence listing:
	$\boxtimes$	contained in the inter	rnational application in written form.
	$\boxtimes$	filed together with the	e international application in computer readable form.
		furnished subsequen	ntly to this Authority in written form.
		furnished subsequen	ntly to this Authority in computer readable form.
		The statement that the international approximation of the international approximation of the statement of th	he subsequently furnished written sequence listing does not go beyond the disclosure pplication as filed has been furnished.
		The statement that the listing has been furnit	he information recorded in computer readable form is identical to the written sequence ished.
4.	The	amendments have re	esulted in the cancellation of:
		the description,	pages:
		the claims,	Nos.:
		the drawings,	sheets:

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5. 🏻	This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
	(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

- 6. Additional observations, if necessary:
- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N)

Yes: Claims
1-22
No: Claims

Inventive step (IS)

Yes: Claims
1-22
No: Claims

Industrial applicability (IA)

Yes: Claims
No: Claims

1-22

2. Citations and explanations

see separate sheet

24).

- **EXAMINATION REPORT SEPARATE SHEET**
- The present application discloses transformed plants capable of producing 1. lysosomal enzymes in the seeds.
- Reference is made to the following documents: 2.
  - D1 (WO 97 10353, cited in the application) discloses the production of lysosomal enzymes in transgenic plants. The examples deal with the expression under a 35S promoter and an inducible promoter and disclose the expression in leaves. Claimed is also a method wherein a lysosomal enzyme is expressed in seeds (claim 1) Similarly, D2 (WO 02 08404) discloses the expression of lysosomal enzymes in leafs of transgenic plants, but also refers to the expression in seeds (p 61, l. 23-
- However, none of these documents actually discloses the expression of lysosomal 3. enzymes in seeds but only refer to seeds as one of a series of possible tissues. Claims 1-22 therefore can be considered to be novel over the available prior art (Article 33(2) PCT).
- It would appear from the present application that the expression of lysosomal 4. proteins in seeds has advantages over the expression in leaves (higher production, stability and solubility of the recombinantly expressed protein, correct glycosylation). These advantages were not derivable from the prior art which does not appear to motivate the skilled person to select seed tissue from the list provided in D1 or D2. The choice of seed as tissue for the expression of lysosomal proteins therefore was not rendered obvious by the prior art, and the subjectmatter of claims 1-22 are considered to be based on an inventive activity (Article 33(3) PCT).